

# Cincinnati VAMC

## Research Service Presentation

**WebDonuts.com**



# Research Service

- Our mission is to improve the quality of care for veterans through medical research.
- There are approximately 100 human, animal, and bench studies at the Cincinnati VA Medical Center.
- Studies are funded through the VA Merit Program, NIH, DOD, industry sponsored, and others.
- Dr. Kathleen Chard, PhD, is our Associate Chief of Staff (ACOS) for Research Service.
- Cincinnati Education and Research for Veterans Foundation (CERV) is the non-profit organization for research funding. Ron Hakes, CEO

# Research Review Committees:

- Research & Development Committee
  - Chair: William Ridgway, M.D.
- Subcommittee on Research Safety
  - Chair: Ken Kaufman, Ph.D.
- Institutional Animal Care & Use Committee (IACUC)
  - Chair: Jennifer McGuire, PhD.
- Institutional Review Board (University of Cincinnati)
  - Chair: Mike Linke, Ph.D.

# Research Personnel

## *Committee Administrator:*

- **Marcilla Lamb , 513-861-3100 ext.6498 [Marcilla.Lamb@va.gov](mailto:Marcilla.Lamb@va.gov)**
- **Program Analyst and Committee Administrator for:**
  - **Research and Development Committee (R&D) and**
  - **Subcommittee on Research Safety (SRS)**
- **WOC and training specialist**

## *Research Compliance Officers:*

- **Terri Heidotting, 513-861-3100 ext.5424 – For Cincinnati VA**
- **Brian Williams, 937-268-6511 ext.2407 – For Chillicothe and Columbus**

# Required Training

## TMS Training:

1. VA Privacy and Information Security Awareness and Rules of Behavior (required every 12 months on anniversary date of completion) TMS Course # 10176
2. Privacy and HIPAA Training (required every 12 months on anniversary date of completion) TMS Course # 10203
3. Organizational Ethics (required every fiscal year) TMS Course #11454  
For Columbus and Chillicothe I will take Integrated Ethics (Patient Privacy and Confidentiality).

Please access the TMS website by going to  
<https://www.tms.va.gov/plateau/user/login.do>.

**NOTE: The Committee Administrator does not have access to TMS training for Chillicothe, Columbus, or Dayton. You will need to send an electronic certificate to the Committee Administrator via email.**

# Required Training (Cont.)

**You must complete BOTH the VA CITI training courses AND the University of Cincinnati CITI courses.**

## **VA CITI Program Training:**

1. VA Human Subjects Protection and Good Clinical Practices (required every **three** years)
2. VA ORD Biosecurity Training (Required only once, during initial setup)

To register with the CITI Program, please read the following instructions below.

3. You will need to start at [www.citiprogram.org](http://www.citiprogram.org). You must register as a new user, if not previously registered.
4. You will need to affiliate with the Cincinnati VA (**Cincinnati, OH-539**) under “Veterans Affairs”. This will then prompt you to answer a series of questions.
  - Once you have answered the questions, you will be assigned “Human Subject Protection Program/Good Clinical Practices” for the VA. The next step will be to go back and affiliate with another institution.

## **University of Cincinnati (UC) CITI Training:**

5. Under “Participating Institutions” you will select “**Greater Cincinnati Academic and Regional Health Centers**”.
  - You will again be asked a series of questions.
  - Once you have answered the questions, you should be assigned “Academic and Regional Health Centers Core Curriculum” and “Human Subjects Research Core Curriculum” at minimum.
  - For specific UC IRB requirements, please contact Claudia Norman at 558-5784 ([claudia.norman@uc.edu](mailto:claudia.norman@uc.edu)).
  - While registering as a new user, if you are prompted for an employee code, you may use “001”.

Please note that you cannot affiliate with both UC and VA simultaneously. You will have to affiliate with one then the other. You will also have to complete the VA ORD Biosecurity Training.

If you have any questions, please contact Marcilla Lamb, 861-3100 ext.6498 [Marcilla.Lamb@va.gov](mailto:Marcilla.Lamb@va.gov)

# Where do you begin with the R&D Submission?

You may submit to the Research and Development Committee (R&DC) at the same time that you submit to the Institutional Review Board (IRB).

The R&D is the scientific review board for human, animal, and bench research studies conducted at the VA.

Every R&DC has an IRB of record that is in charge of the protection of human subjects. University of Cincinnati IRB is the IRB of record for the Cincinnati VAMC, Chillicothe VA, Dayton VA, and the Chalmers Columbus VA.

# R&D Submission (Cont.)

## Deadlines:

The deadline for submission to ensure it reaches all the committees in succession is the third Friday of the prior month.

Note: the UC IRB meets weekly and does not have a submission deadline.



# R&D Submission (Cont.)

Once IRB has approved your project, please submit the **approved** documents and IRB approval letter to the Committee Administrator , who will forward the study to the R&D Committee for their review.

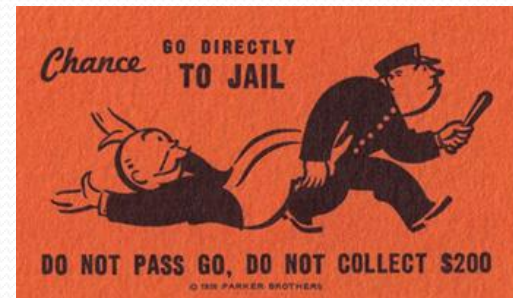
All documents are submitted **ELECTRONICALLY** via e-mail to the Committee Administrator.

**PLEASE DO NOT SEND THE DOCUMENTS IN BITS  
AND PIECES**



NO *research* project can begin without these three approval letters.

1. IRB Approval Letter
2. SRS Approval Letter
3. R&D Approval Letter



If you collect your data without all necessary approvals, this is an issue of non-compliance.

## Any Questions?

- Marcilla Lamb, Committee Administrator (513)475-6498
- Terri Heidotting, Research Compliance Officer (513)861-3100 ext: 5424



# SUPPORTING VA RESEARCH.

It's what we do

**RON HAKES**

THURSDAY, NOVEMBER 30, 2017

CINCINNATI EDUCATION &  
RESEARCH FOR VETERANS  
FOUNDATION "CERV"



# VA: A CLOSED “sandbox”



# CONGRESS MANDATE - STOP THE MADNESS.

Title 38 U.S.C sections 7361 through 7366

Nonprofit Research and Education  
Corporations (NPC) established at VA medical centers.

NPCs exist to provide VA medical centers with flexible funding mechanisms for the conduct of, and to facilitate functions related to the conduct of, approved research and education at one or more VA medical centers. NPCs are not owned or controlled by the Federal government, nor are they an agency or instrumentality of the Federal government.

# 1991: CERV OPEN FOR BUSINESS



# WHAT KIND OF RESEARCH DOES CERV SUPPORT?

- **GRANTS**
  - NIH & DoD
- **CRADA** (*Cooperative Research and Development Agreements*)
  - **Sponsored Studies**
    - Industry: Merck, J&J, etc.
    - Foundational: ACS, Heart, United Way, etc.
- **Private and Corporate Grants/Donations**
  - Hale, Gates, etc.
- **CERV Sponsored Grants**
  - Educational
  - Seed Funds



- **Our Services:**
  - **Financial Management**
    - **Accounting, invoicing, purchasing, payroll, HR and benefits, travel and conference support.**
    - **Quarterly reports**
    - **Coordinator 24 hour access to documents and study information through CERV Quickbase online.**
    - **Negotiations, budgeting, contracting, communications, legal support.**

**Ronald W. Hakes, CPM, CSSBB**

**CERV**

**Executive Director & CEO**

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